

REMARKS

I. INTRODUCTION

Claims 4-8, 10, 15-32, 36, 37, 39, 40, and 42-45 are pending in the present application. In light of the following remarks, Applicants respectfully submit that all presently pending claims are in condition for allowance.

II. THE 35 U.S.C. § 112 REJECTION SHOULD BE WITHDRAWN

Claims 39 and 40 stand rejected under 35 U.S.C. §112, second paragraph, for being indefinite. Specifically, the Examiner refers to the concept of “the droplets being supplied within the high velocity jet of gas laterally of the direction of the flow of said high velocity jet of gas.” (See 12/15/08 Office Action, p. 2). Applicants respectfully disagree. It is evident from Figures (e.g., Figures 1 to 5) that the membrane producing droplets (i.e., membrane 22 in Figure 1, is laterally mounted with respect to the longitudinal nozzle that carries the flow of high velocity gas. Accordingly, one skilled in the art would understand that the droplets are supplied to the high velocity jet of gas laterally of the direction of the flow of the high velocity jet of gas. Thus, the withdrawal of this rejection is respectfully requested.

III. THE 35 U.S.C. § 103(a) REJECTIONS SHOULD BE WITHDRAWN

Claims 4-8, 10, 15-32, 36, 37, 39 and 40 stand rejected under 35 U.S.C. §103(a) for being obvious over Ross et al. (U.S. Patent No. 5,261,601) in view of Bellhouse et al. (U.S. Patent No. 5,630,796).

Claim 36 recites, “[a] method for needleless injection of a liquid substance into a target biological tissue, the method comprising: generating droplets of the liquid substance; accelerating the droplets of the liquid substance, at a velocity sufficiently high to inject the droplets of the liquid substance into the target biological tissue; and directing the droplets of the liquid substance toward a surface of the target biological tissue at the

sufficiently high velocity to inject the droplets of the liquid substance into the target biological tissue; wherein generating the droplets of the liquid substance comprises injecting a pressurized gas from a pressurized source into a reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through at least one micro-orifice of a perforated membrane to thereby produce a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets.”

Ross discloses a dispensing apparatus such as a hand-held dispensing apparatus for oral inhalation. (See Ross, Abstract). The dispensing apparatus comprises a chamber for containing a liquid to be dispensed, a perforated membrane defining a front wall of the chamber and a vibrating transducer for vibrating either the perforated membrane or a rear wall of the chamber so as to eject droplets of the liquid through the holes of the perforated membrane. (See Id.).

Bellhouse discloses a method for delivering powder transdermally with needleless injector having a membrane that is ruptured by pressure, from an energy mechanism such as for example from a gas cartridge. (See Bellhouse, Abstract).

The Examiner argues that it would be obvious to a person of ordinary skill in the art to modify the device or Ross with the energy mechanism of Bellhouse to use gas pressure to move the liquid substance through the perforated membrane.

However, Ross discloses, “... this droplet size being suitable for delivery of atomized products to the lungs of a patient.” (See Ross, col. 7, ll. 13-15). It is clear from this disclosure that the delivery of the atomized products is made by oral inhalation and not by injection, as in the claimed invention. That is, Ross never intends to have the droplets injected into the lungs of a patient, but rather intends for the droplets to be of an adequate size to reach the lungs of a patient through inhalation (See Id., lines 34-35).

It is, therefore, unclear how the Examiner would modify Ross in view of Bellhouse since the basic purpose of the Ross device is completely different from that of the claimed invention.

Notwithstanding, while it is indeed possible to modify the device of Ross to incorporate a gas cartridge as taught by Bellhouse, it is submitted that the result would either destroy the purpose of Ross' inhalation device or differ from the claimed invention.

Indeed, on the one hand, mounting a cartridge similar to Bellhouse to Ross' inhalation device would have the following effect. In Ross, a vibrating transducer produces, through a perforated membrane, low-velocity droplets for the purpose of inhalation by the patient. Ross teaches no rupture of this perforated membrane. In contrast, Bellhouse teaches the rupture of the membrane and, therefore, if the teaching of Bellhouse is applied to Ross, the membrane of Ross would rupture and no droplets would be produced through this perforated membrane. Consequently, the released gas could not be used to accelerate droplets that do not exist. Obviously, such a combination would not, in separate steps, produce and accelerate droplets in a manner suitable for injection within the patient's biological tissue. In the same manner, such a combination would not be capable of producing low-velocity droplets suitable for inhalation.

On the other hand, should a reduced pressure cartridge (which is not taught by Bellhouse and would therefore require further modification and adaptation to the cartridge) be mounted to Ross' device to render the atomized mist suitable for oral inhalation, the resulting device would be different from the presently claimed invention since the claimed invention, as claimed in claims 36 and 37, requires the acceleration of the droplets of the liquid substance at a velocity sufficiently high enough to inject the droplets of the liquid substance into the target biological tissue. Therefore, Applicants respectfully submit that Ross and Bellhouse, taken alone or in combination, fail to disclose or suggest "directing the droplets of the liquid substance toward a surface of the target biological tissue at the sufficiently high velocity to inject the droplets of the liquid

substance into the target biological tissue,” as recited in claim 36 and, similarly, in claim 37 and that these claims are allowable.

Claim 39 recites “[a] method for needleless injection of a liquid substance into a target biological tissue, the method comprising: generating a high velocity jet of gas; generating droplets of the liquid substance; supplying and conveying the droplets of the liquid substance into the high velocity jet of gas; and guiding the high velocity jet of gas through a channel toward a surface of the target biological tissue for injecting the conveyed droplets of the liquid substance into the target biological tissue; wherein generating the droplets of the liquid substance comprises: containing the liquid substance into a reservoir; interposing a perforated membrane between the reservoir and the channel in such a manner that the flow of the high velocity jet of gas is guided along a face of the perforated membrane on a side of the perforated membrane opposite to the reservoir of the liquid substance; and pressurizing the reservoir containing the liquid substance to force the liquid substance from the liquid reservoir through the perforated membrane to thereby produce a jet of the liquid substance that transforms into a stream of the droplets supplied within the high velocity jet of gas laterally of the direction of the flow of said high velocity jet of gas.”

As previously mentioned, modifying Ross in view of Bellhouse is either improper or does not render the claimed invention obvious.

It is respectfully submitted that there would be no basis to combine the references of Ross and Bellhouse. Contrary to the Examiner’s comments, Ross does not describe a device and method for a needleless injection of a liquid substance. As indicated in the foregoing comments, the velocity of the droplets generated by the transducer of Ross is not sufficiently high for the droplets to penetrate a surface of a biological tissue. This is due to the fact that the dispensing apparatus is used to generate droplets which are subsequently inhaled through the mouth; no inhalation would be possible if the droplets would penetrate the mouth’s biological tissues by being injected therein. More specifically, there would be no basis to combine a dispensing apparatus as taught by Ross

to produce a mist of droplets suitable for inhalation by a patient with a needleless transdermal power injector as taught by Bellhouse. It is believed that one of ordinary skill in the art would not consider an apparatus for producing a mist of droplets for inhalation when trying to construct a device for injecting droplets of a liquid substance into a biological tissue. It is respectfully submitted that the combination of Ross and Bellhouse also fails to render claims 4-8, 10, 15-32, 39 and 40 obvious and that these claims are, therefore, allowable.

Claims 42-45 stand rejected under 35 U.S.C. §103(a) for being obvious over Ross in view of Garitano et al. (U.S. Patent No. 6,689,095).

Garitano discloses a permanent makeup and tattoo device using a compressed gas actuated piston as an energy mechanism.

The Examiner states that it would have been obvious to a person of ordinary skill in the art to have modified the pressure source of Ross with the energy mechanism of Garitano to control the liquid injection. (See 12/15/08 Office Action, p. 6).

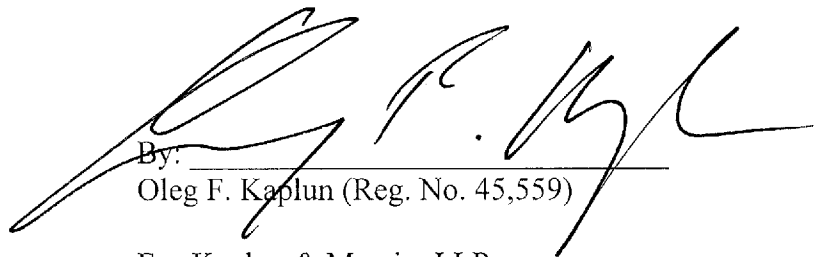
As is apparent from the foregoing comments, Applicants respectfully submit that Ross is not suitable as a primary reference, at least since it discloses an inhalation device. As previously mentioned with regard to Bellhouse, even if Ross' inhalation device was modified with the piston containing energy mechanism of Garitano, the resulting device would either destroy the utility of Ross or lack the power to inject the droplets of the liquid substance as seen in the claimed invention. Furthermore, Garitano produces and injects one drop at a time ("a microdroplet") (See Garitano, col. 14, ll. 47-50) and, therefore, fails to teach production of "*a jet of the liquid substance, wherein the jet of the liquid substance transforms into a stream of the droplets,*" as recited in claim 42 and, similarly, claims 43-45. Therefore, it is respectfully submitted that the combination of Ross and Garitano does not render claims 42-45 obvious and that these claims are allowable.

CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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A large, stylized handwritten signature in black ink, appearing to read 'O. F. Kaplun', is written over a horizontal line.

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